REMARKS

Claims 17-21 have been previously withdrawn. Accordingly, Claims 1-16 are pending.

Double Patenting

Claims 1-16 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/570,505. (Office Action page 2.)

Applicants request that the examiner hold the provisional rejections made under the judicially created doctrine of obviousness-type double patenting in abeyance until allowable subject matter is identified in the instant application. Once allowable subject matter has been identified, applicants will evaluate whether to file a terminal disclaimer or to provide arguments in view of the claims pending at that time.

Anticipation under 35 U.S.C. § 102(e)

Claims 1-16 are rejected under 35 U.S.C. §102(e) as being allegedly anticipated by U.S. Publication No. 2005/0273275 to Afeyan *et al.* According to the examiner, Afeyan *et al.* teaches a method of developing drugs by using multiple biomarkers and profiling with mass spectrometry. The examiner asserts that all of the features of the claims are taught by Afeyan *et al.* (Office Action, pages 3-4.)

As previously submitted by the applicants, Afeyan *et al.* does not teach all of the steps of the pending claims. Applicants are unable to locate where in the disclosure of Afeyan *et al.* 1) the effect of drugs is determined, 2) the preparation of drugs is described, or 3) where the effect of the drug on a disease is determined.

According to 37 CFR 1.104, "When a reference is complex or shows or describes inventions other than that claimed by the applicants, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified." The examiner is kindly requested to specify specifically where such features are taught in Afeyan *et al.* if the present rejection is to be maintained.

In the December 1, 2009 Office Action, the examiner pointed to paragraphs 4 and 5 of Afeyan *et al.* as disclosing developing drugs for diseases with multiple biomarkers and profiling with mass spectrometry, and to paragraph 6 as disclosing multivariate analysis of the data. A claim is anticipated only if each and every element of the claim is found in a single prior art reference. Applicants fail to see how these paragraphs teach each and every element of the claims. Although Afeyan *et al.* mentions the term "multivariate analysis" in paragraph 6, the reference does not describe all of the steps of the claims.

Figures 1 and 2 of Afeyan *et al.* describe a system for developing a profile of a biological system. As shown in Figures 1 and 2, a single step of multivariate analysis is disclosed. Nothing in the figures, or the rest of the disclosure, teaches a method comprising the four separate steps of pending Claim 1.

Applicants respectfully assert that the examiner has not made a proper anticipation rejection. The standard for establishing anticipation is set forth in MPEP §2131 as follows:

> A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference…The identical invention must be shown in as complete detail as is contained in the...claim…The elements must be arranged as required by the claim…(Quotation marks and references omitted.) (Emphasis added.)

The U.S. Court of Appeals for the Federal Circuit recently reiterated the standard by which to establish an anticipation rejection. In *Net Moneyin, Inc. v. Verisign, Inc. et al.* No. 2007-1565 (Fed. Cir. 2008), the court stated that in order for a reference to be anticipatory, it must "show all of the limitations of the claims arranged or combined in the same way as recited in the claims…"

Thus for a reference to anticipate a claim, the reference must: (a) describe each and every element of the claim, and (b) the elements must be "arranged or combined in the same way" as recited in the claim. Afeyan *et al.* does neither. Therefore, the examiner has not met this standard. The examiner appears to be improperly ignoring many of the claim elements in issuing the present rejection as steps a) through d) are clearly not disclosed in Afeyan *et al.*

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) are respectfully requested.

Obviousness Rejection under 35 U.S.C § 103(a)

On page 5 of the Office Action, the examiner rejects Claims 1-16 as being obvious over Borisy *et al.* (2003/0096309). The examiner acknowledges that the pending claims differ from Borisy *et al.* in that mass spectrometry is used to test the samples. However, the examiner alleges that it would have been obvious to test the samples of Borisy *et al.* with mass spectrometry at the time of the invention because Borisy *et al.* shows testing with various cell-based assays.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Borisy *et al.* does not teach all of the limitations of independent Claim 1, in particular the

step of determining a biological profile of a disease. Thus, the obviousness rejections cannot stand.

The examiner's response to applicants' arguments submitted April 1, 2010 is that Borisy *et al.* correlate the drugs with their effects. Even if one were to assume that Borisy *et al.* do correlate the drugs with their effects, applicants fail to see how this teaches the step of determining a biological profile of a disease.

In addition, the method of Borisy *et al.* is limited to obtaining only partial synergetic information by random screening efforts, and fails to identify the interplay within a living system that can only be observed on a system wide level.

Applicants submit that Borisy *et al*. does not teach all of the claim limitations; and thus, fails to render the claims obvious. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Written Description Rejection

On pages 6-7 of the Office Action, the examiner rejects Claims 1-16 for lack of written description. According to the examiner, the specification does not describe the claimed subject matter in a way to reasonably convey possession.

An objective standard for determining compliance with the written description requirement is whether "the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The examiner has failed to establish that a skilled person would not recognize from the description that applicants invented what is claimed.

In the April 1, 2010 response to Office Action, applicants clearly indicated the passages within the application that describe how the claimed method is to be performed, i.e., pages 13 and 14 of the specification. Applicants submit herewith a review from one of the inventors that demonstrates the surprising outcome of combining atorvastatin and fenofibrate in a living system (van der Greef *et al.*, *Nature Reviews Drug Discovery* (2005) *4*:961-967). For example, Figure 3 of van der Greef *et al.* shows that the combination drug therapy is much more beneficial than each of the two drugs alone. This outcome cannot be observed in a cellular system.

Thus, applicants submit that the claims meet the written description requirements. Thus, withdrawal of the rejection and reconsideration are respectfully requested.

If resolution of any remaining issues is required prior to the examination of the application, it is respectfully requested that the examiner contact applicants' attorney at the telephone number provided below.

Respectfully submitted,

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